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18. (New) The method according to claim 2 wherein the mixing of step c) is accomplished by solvent mixing.

19. (New) The method according to claim 2 wherein step e) is accomplished manually.

20. (New) The method according to claim 2 wherein step e) is accomplished with use of a machine.

21. (New) The composite material according to claim 1 wherein the resorbable polymeric reinforcing component is in fiber form with a fiber diameter between $4\mu\text{m}$ and $800\mu\text{m}$.

22. (New) The composite material according to claim 21 wherein the fiber diameter is between $20\mu\text{m}$ and $500\mu\text{m}$.

REMARKS

Claims 1-2 have been examined in the above-referenced action. In response to this action, Applicants have herein amended claims 1-2 and added new claims 3-22. Support for these amendments exists in the specification, for example, at page 4, lines 11-24; page 5, line 23 continuing to page 7, line 24; pages 14-16; and Figure 1. Reconsideration and allowance of this application is therefore respectfully requested.

Claims 1-2 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 4,968,317 (hereafter "the '317 patent") or claims 1-7 of U.S. Patent No. 5,084,051 (hereafter "the '051 patent"). According to the Examiner, the conflicting claims are not identical, but they are not

patentably distinct from each other because both patents teach surgical composite materials made of resorbable polymeric matrix and reinforcing elements similar to that of the invention.

Claims 1 and 2 have been amended to more specifically recite Applicants' invention and, as amended, Applicants' respectfully submit that those claims are now in condition for allowance.

It is initially noted that the '317 patent has been reexamined and a reexamination certificate, dated January 5, 1999, has been issued. For the Examiner's convenience, a copy of this certificate is submitted herewith. As indicated therein, claims 1, 3 and 4-8 of the '317 patent have been canceled, claim 2 has been amended and new claims 9-17 have been added.

Independent claims 2 and 9 of the '317 patent (reexamined) are directed to:

2. Surgical device comprising a material selected from the group of resorbable polymer, resorbable copolymer, and mixtures thereof said material being drawn in solid state to a composite containing oriented, at least partially fibrillated structural units, wherein the drawn composite is formed into a bone surgery device being in the form selected from the group consisting of rods, plates, screws, nails, tubes, and clamps.

9. Surgical device comprising a material selected from the group of resorbable polymer, resorbable copolymer, and mixtures thereof, said material being drawn in solid state to a composite containing oriented, at least partially fibrillated structural units, wherein the drawn composite is formed into the device, said device having a segment having an at least partially fibrillated profiled surface.

It is respectfully asserted that the Applicants' amended claims, which more specifically recite Applicants' invention and a method of its manufacture, are patentable over the '317 patent (reexamined). Applicants' independent claim 1 requires:

1. A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: at least one resorbable polymeric matrix component including therein at least one resorbable polymeric reinforcing component as a

large scale reinforcing element and at least one bioceramic or bioglass reinforcing component as a smaller scale reinforcing element, said bioceramic or bioglass reinforcing component having coarse particles, and said polymeric reinforcing component being distinguishable from the composite material as a whole.

Claims 2-15 and 17-22 depend either directly or indirectly therefrom and specify further detailed features of that which is recited in claim 1. Applicants' independent claim 16 is particularly directed to:

16. A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: at least one resorbable polymeric matrix component including therein at least one resorbable polymeric reinforcing component in fiber form and at least one bioceramic or bioglass reinforcing component having coarse particles, wherein the diameter or particle size of the resorbable polymeric reinforcing component is greater than the diameter or particle size of the bioceramic or bioglass reinforcing component, and the polymeric reinforcing component is distinguishable from the composite material as a whole, said composite material further having increased mechanical strength.

As amended, Applicants' claims require at least two different, particularly defined reinforcing components in a resorbable polymeric matrix, wherein the polymeric reinforcing component is distinguishable from the composite material as a whole. Moreover, the bioceramic or bioglass reinforcing component of the invention is more particularly defined as having coarse particles. As described in Applicants' specification at page 6, lines 14-22:

[t]he defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

For all of the above reasons, Applicants respectfully submit that amended claims 1-2 and new claims 3-22 are patentable over the claims of the '317 patent. Accordingly, the Examiner's rejection under the doctrine of obviousness-type double patenting based on the '317 patent is believed to be met and should be withdrawn.

Similarly, the Examiner's rejection of Applicants' claims under the doctrine of obviousness-type double patenting based on the '051 patent also should be withdrawn for the following reasons.

Applicants' pending claims have been described above in detail.

The claims of the '051 patent are directed to a biocomposite material for bone surgical applications. Claim 1, the only independent claim, requires:

1. Biocomposite material for bone surgical applications, which biocomposite comprises:
 - at least one bioceramic layered component and
 - at least one material component layer which has been manufactured of at least one polymer which material component has at least one common boundary surface with the bioceramic component; wherein
 - the material component comprises at least reinforcement elements which have been manufactured of resorbable material selected from the group consisting of polymer, copolymer, polymer mixture, and ceramic material and mixtures thereof and that
 - the material component can include binding material which is manufactured of resorbable polymer, copolymer or polymer mixture and that
 - whereby the material component is porous at least in tissue conditions, and wherein
 - the bioceramic component is at least partially porous and that
 - the material component has a surface contact connection with the bioceramic component in such a way that the part of the porosity of the bioceramic component, which is to be put against the bone tissue, is free of the material component.

The claimed invention of the '051 patent is a particularly defined layered biocomposite material requiring "a surface contact connection with the bioceramic component in such a way that the part of the porosity of the bioceramic component, which is to be put against the bone tissue, is free of the material component." Applicants' presently claimed invention, however, requires at least two different, particularly defined reinforcing components in a resorbable polymeric matrix, wherein the polymeric reinforcing component is distinguishable from the composite material as a whole and the bioceramic or bioglass reinforcing component has coarse particles. Nor is Applicants' particularly claimed method of manufacturing such a composite material suggested. Accordingly, in view of the above amendments to the claims, reconsideration and withdrawal of the rejection is believed to be warranted.

Claims 1-2 have also been rejected under 35 U.S.C. § 103 as rendered obvious by the '317 patent or the '051 patent. According to the Examiner:

'317 teaches a surgical material of resorbable polymer comprising a matrix phase which binds to a reinforcing elements. The resorbable polymer is partially fibrillated. The resorbable and the ceramic reinforcing materials of the instant invention are disclosed (entire patent, particularly abstract, cols. 2-8 and fig. 2). The material has higher strength and elastic modulus than those of the known implant materials and can be used for osteosynthesis.

'051 teaches a biocomposite material for bone surgical applications containing a bioceramic component and a material component of reinforcing elements made up of resorbable polymer. The reinforcing elements are fibrillated and bound to the bioceramic by application of heat and pressure so as to compensate for the brittleness of the bioceramics (see entire patent, especially cols 1-15). Therefore, the instant invention would have been obvious for a skilled artisan from the teachings of '317 or '051.

In response to the rejection of its claims, Applicants have amended claim 1 to more particularly recite its invention, *i.e.*, at least two different reinforcing components in a

resorbable polymeric matrix, wherein the polymeric reinforcing component is distinguishable from the composite material as a whole and the bioceramic or bioglass reinforcing component has coarse particles. Likewise, Applicants have amended claim 2 to more particularly recite the claimed method of manufacturing such a composite material. Thus, as amended, Applicants respectfully submit that claims 1-2, and new claims 3-22, are patentable over the disclosure of the '317 patent, including the parts cited by the Examiner, *i.e.*, the abstract, cols. 2-8 and Figure 2 of the '317 patent. Accordingly, the rejection is believed to be met and should be withdrawn.

Applicants further assert that the '051 patent does not disclose nor suggest the presently claimed invention for the foregoing reasons. For example, the '051 patent discloses a particular layered surgical biocomposite material. A comparison of the figures of the '051 patent with Figure 1 of the present invention schematically illustrates such a distinction.

Moreover, the examples set forth in Applicants' specification, at pages 8-13 of the specification, demonstrate the advantageous strength of composite materials manufactured in accordance with the present invention.

In view of the foregoing amendments and remarks, it is respectfully submitted that each of the pending claims 1-22 of the present application is now in condition for allowance. Issuance of a Notice of Allowance is therefore requested. The Examiner is invited to call the undersigned attorney at (212) 908-6320 if there are any questions concerning this amendment.

Respectfully submitted,

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